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| APPLICATION NO. FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|-----------------------------|-----------------|-------------------------|---------------------|------------------|--|--|
| 10/018,608 07/30/2002 | | Ruth Duncan | 5585-61534 | 5088 | | |
| 24197 | 7590 05/01/2003 | | | | | |
| KLARQUIST SPARKMAN, LLP | | | EXAMINER | | | |
| SUITE 1600 | MON STREET | | PESELEV, ELLI | | | |
| PORTLAND, OR 97204 | | | ART UNIT | PAPER NUMBER | | |
| | | | 1623 | 7 | | |
| | | DATE MAILED: 05/01/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | Application No | | Applicant(s) | | | | |
|---|--|--|---|--|---|-----------------|--|--|--|
| | | | 10/018,608 | | DUNCAN ET AL. | | | | |
| | Office Action Summar | γ | Examiner | | Art Unit | | | | |
| | | | Elli Peselev | | 1623 | | | | |
| Perio | The MAILING DATE of this con od for Reply | nmunication appe | ears on the cov | er sheet with the c | orrespond nce ad | ldress | | | |
| T - | A SHORTENED STATUTORY PERIOD STATUTORY P | MUNICATION. visions of 37 CFR 1.13 s communication. thirty (30) days, a reply mum statutory period wi or reply will, by statute, onths after the mailing | 6(a). In no event, howeverthe the statutory mand will expir cause the application | wever, may a reply be tim inimum of thirty (30) day: a SIX (6) MONTHS from to become ABANDONE | nely filed s will be considered timel the mailing date of this c D (35 U.S.C. § 133). | | | | |
| 1 |) Responsive to communication | (s) filed on | | | | | | | |
| 2a |)☐ This action is FINAL . | 2b)⊠ Thi | s action is non- | final. | | | | | |
| |) Since this application is in con closed in accordance with the osition of Claims | | | | | ne merits is | | | |
| 4 |)⊠ Claim(s) <u>1-13 and 16-23</u> is/are | pending in the | application. | | | | | | |
| | 4a) Of the above claim(s) | _ is/are withdraw | n from conside | ration. | | | | | |
| 5 | Claim(s) is/are allowed. | | | | | | | | |
| 6 | 6)⊠ Claim(s) <u>1-13 and 16-23</u> is/are rejected. | | | | | | | | |
| 7 |) Claim(s) is/are objected | to. | | | | | | | |
| 8 | Claim(s) are subject to r | estriction and/or | election requir | ement. | | | | | |
| | ication Papers | | · | | | | | | |
| 9 |) The specification is objected to | by the Examiner | | | | | | | |
| 10 |)☐ The drawing(s) filed on is | a/are: a)□ accep | ted or b) dbje | cted to by the Exa | miner. | | | | |
| | Applicant may not request that a | ny objection to the | drawing(s) be h | eld in abeyance. S | ee 37 CFR 1.85(a). | | | | |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner. | | | | | | | | | |
| | If approved, corrected drawings a | • | - | ction. | | | | | |
| |)☐ The oath or declaration is object | | aminer. | | | | | | |
| Prior | ity under 35 U.S.C. §§ 119 and 12 | D | | | | | | | |
| 13 |) Acknowledgment is made of a | claim for foreign | priority under 3 | 35 U.S.C. § 119(a |)-(d) or (f). | | | | |
| | a) ☐ All b) ☐ Some * c) ☐ None | e of: | | | | | | | |
| | Certified copies of the pr | iority documents | have been red | eived. | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14) | Acknowledgment is made of a cl | aim for domestic | priority under | 35 U.S.C. § 119(e | e) (to a provisiona | l application). | | | |
| 15 | a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | | |
| | nment(s) | | processing and of | 2.3.3.33 120 | mirror wit 1 to 14 | | | | |
| 1) 2) | Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Rev Information Disclosure Statement(s) (PTO-14 | | 4) [5) [6) [| | v (PTO-413) Paper No Patent Application (PT | | | | |
| | and Trademark Office (Rev. 04-01) | | Part o | of Paper No. 7 | | | | | |

Application/Control Number: 10/018,608

Art Unit: 1623

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The disclosure is objected to because of the following informalities: the section titled "BRIEF DESCRIPTION OF THE DRAWINGS" is missing on page 6 of the specification.

Also, TABLE 2 is improperly set forth on page 14 of the specification, after the claims.

Appropriate correction is required.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cancer, does not reasonably provide enablement for treating any disorder or diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is a god reason to doubt that a dextrin polymer anti-cancer drug conjugate of claim 1 is useful for treating any other diseases or disorders other than cancer.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Application/Control Number: 10/018,608

Art Unit: 1623

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by the International Patent No. WO 98/56424A.

The International Patent discloses the claimed dextrin polymer drug conjugate.

Claims 1-13 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the International Patent NO. WO 98/56424A.

The International Patent discloses a succinoylated dextrin polymer drug conjugate but does not disclose conjugates wherein succinoylation is at least 20mol%. However, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to vary the degree of succinoylation of dextrin, because such a person would have expected the resulting compounds to have similar utility.

Application/Control Number: 10/018,608

Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev April 30, 2003

> ELLI PESELEV PRIMARY EXAMINER GROUP 1800

Page 4